IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of)
)
GRAHAM EDMUND KELLY)
)
Application No. 08/338,567)
)
Filed: January 12, 1995)
)
For: HEALTH SUPPLEMENTS)
CONTAINING PHYTO-OESTROGENS)
ANALOGUES OR METABOLITES)
THEREOF)

Examiner: J. Wilson

Group Art Unit: 1211

MAR 2 1 1997

DECLARATION OF GRAHAM EDMUND KELLY UNDER 37 C.F.R. §1.132

I, Graham Edmund Kelly, a citizen of the Commonwealth of Australia, residing at 1/47 Coolawin Road, Northbridge, New South Wales, Commonwealth of Australia, do solemnly and sincerely declare as follows:

1. I am Chief Executive Officer of Norvet Ltd. and am the inventor of the subject application.

2. I am a research scientist and hold the degrees of Bachelor of Science (Vet) from the University of Sydney (1968); Bachelor of Veterinary Science from the University of Sydney (1969); and Doctor of Philosophy from the University of Sydney (1972). I have worked in the field of medical and veterinary research for approximately twenty-five years.

3. I have read the Office Action in connection with U.S. Patent Application No. 08/338,567 by Examiner Wilson, dated 10 September 1996.

4. The health supplement composition comprising an extract from soya or clover as claimed in the patent application has been used in a series of therapeutic treatments conducted at my request and/or under my supervision. Details of these treatments are set forth below.

Compositions

Compositions comprising an extract of soya or clover were prepared in accordance with Examples 1 and 2 at pages 18 and 19 of the subject application 08/338,567. These compositions, for convenience referred to as "the inventive composition", were prepared comprising 40 mg, 80 mg, 120 mg, 160 mg and 240 mg of phyto-estrogen.

Treatments

Prostate Cancer

Two patients diagnosed with prostate cancer were treated initially with the inventive composition comprising 240 mg per day, and subsequently 120 mg per day phyto-estrogen. The PSA levels, a marker for prostate cancer, were stabilized in these patients and there has been no rise in the PSA levels subsequently. This demonstrates the treatment of prostatic cancer in these individuals.

A further patient diagnosed with malignant prostate cancer (PSA 13.1 μg/L) was treated with the inventive composition. The patient was treated with the composition comprising 160 mg per day phyto-estrogen, seven days prior to prostatectomy. Histological comparison was made of the pre-operative needle biopsy and the prostatectomy specimen. The needle biopsy revealed low grade infiltrating adenocarcinoma. The prostatectomy specimen showed mild patchy microvacuolation and prominent apoptosis (programmed cell death). Lymph nodes were negative for malignancy. The degenerative changes in the prostatectomy specimen, especially the apoptosis, show treatment of the prostatic cancer.

Benign or Cystic Breast Disease

A patient with benign or cystic breast disease was treated with 160 mg of the inventive composition administered orally on a daily basis. The patient exhibited no breast tenderness, which was maintained when the dosage level was reduced to 80 mg. Her symptoms did not return and she continues to have relief from mastalgia.

Pre-Menstrual Syndrome (PMS)

Nine women were treated with 80 mg per day of the inventive composition and were screened for the well-described symptoms of PMS including psychological, psychiatric, gynecological and personal status. Relief from PMS in these various symptoms was observed across the treatment group.

Menopause

Eight menopausal women were divided into two groups of four and treated with either 40 mg or 160 mg of the inventive composition administered orally on a daily basis. Four patients were also treated with a placebo composition. Indicators measured were incidence or severity of hot flushes, night sweats. Green score, vaginal pH, vaginal cytology and mean cholesterol levels across the treatment groups. A significant change in menstrual symptoms was observed and a dose response change was observed between the 40 mg and 160 mg dosage range. This indicating that 160 mg per day was the most effective dosage for treatment of menopausal symptoms.

5. These studies show that a composition according to the invention described and claimed in U.S. Patent Application No. 08/338,567 is effective in the treatment of:

- Prostate cancer

- Benign or cystic breast disease (mastalgia)
- Pre-menstrual syndrome
- Symptoms of menopause

6. As shown in the Examples 3 and 4 at pages 19 and 20 of the subject application 08/338,567, a composition according to the invention was effective in the treatment of elevated levels of cholesterol in the blood stream.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and such willful false statements may jeopardize the validity of the application or patent issuing thereon.

3.3.97
DATE

GRAHAM EDMUND KELLY